K981579

JUL 9 1998

SECTION 7

510(k) Summary of Safety and Effectiveness

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency. MODIFIED DEVICE NAME: ENDOPOUCH PRO Specimen Retrieval Bag PREDICATE DEVICE NAME: ENDOPOUCH II Specimen Retrieval Bag and Auto Suture ENDO CATCH Specimen Retrieval Bag
Device Description	The ENDOPOUCH PRO device is comprised of a flexible plastic bag with a large, easily accessible opening, a push rod handle and an introducer tube. The push rod and handle allow for single hand deployment.
Intended Use	The ENDOPOUCH PRO Specimen Retrieval Bag is intended for use during general laparoscopic surgical procedures as well as the collection and extraction of tissue specimens such as the appendix, gall bladder, ovaries, fibroid tumors, other tissues and calculi.
Indications Statement	The ENDOPOUCH PRO Specimen Retrieval Bag is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as the appendix, gall bladder, ovaries, fibroid tumors, other tissues and calculi during laparoscopic surgical procedures.
Technological characteristics	The modified device has the same technological characteristics as the predicate devices. The form, fit and function is similar.

Continued on next page

Performance Data	Pre-clinical in vivo as well as bench top testing has been performed to verify that the product meets the performance requirements described. It was determined that the device has greater bag strength than either predicate device.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate devices under the Federal Food, Drug, Cosmetic Act.
Contact	Gregory R. Jones Director of Regulatory Affairs ETHICON, Inc. Rt. #22 West Somerville, New Jersey 08876-0151
Date	May 1, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
Route 22, West
Somerville, New Jersey 08876

Re: K981579
Trade Name: Endopouch Pro Specimen Retrieval Bag
Regulatory Class: II
Product Code: MDM
Dated: May 1, 1998
Received: May 4, 1998

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K981579

Device Name: ENDOPOUCH PRO Specimen Retrieval Bag

Indications for Use: ENDOPOUCH PRO Specimen Retrieval Bag is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as appendix, gall bladder, ovaries, fibroid tumors, other tissues and calculi during laparoscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use X

(Optional Format 1-2-9G)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981579